



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 10, 2020

Krista D. Coleman  
Agent  
Palmero Healthcare LLC  
120 Goodwin Place  
Stratford, CT 06615

Subject: Label Amendment: Emerging Viral Pathogens Claim  
Product Name: DisCide ULTRA Disinfecting Towelettes  
EPA Registration Number: 10492-4  
Application Date: 03/26/2020  
Decision Number: 561245

Dear Ms. Coleman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Adenovirus Type 2 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at [disinfectantslist@epa.gov](mailto:disinfectantslist@epa.gov).

Sincerely,



Demson Fuller, Product Manager 32  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

# DisCide ULTRA Disinfecting Towelettes

## A One-Step Disinfectant – Cleaner – Decontaminant

Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal\*

DisCide ULTRA Disinfecting Towelettes are non-woven disposable towelettes impregnated with a dual chain quaternary ammonium/high level alcohol solution.

**Healthcare Use in Health Care & Alternate Care Settings** such as hospitals, intensive care units, emergency medical settings, central supply, laboratories, clinics, nursing homes, and dental suites where control of the cross-contamination hazards between treated surfaces is required. **Consumer Use** on hard, non-food-contact surfaces in kitchens, food service areas and bathrooms and other related hard, non-food-contact surfaces such as shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, and door knobs and handles. **DisCide ULTRA Disinfecting Towelettes** eliminate odors and are effective against the following pathogens on hard non-porous, contact surfaces when used as directed at the contact times listed below:

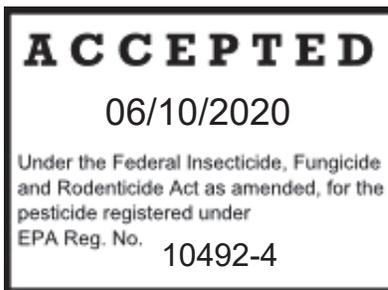
- |  |                  |  |           |
|--|------------------|--|-----------|
| ➤ Tuberculosis bacteria<br>(Mycobacterium bovis)         | (1 min. at 20°C) | ➤ MRSA<br>(Methicillin Resistant<br>Staphylococcus aureus)             | (1 min.)  |
| ➤ Staphylococcus aureus (Staph)                          | (1 min.)         | ➤ VRE<br>(Vancomycin Resistant<br>Enterococcus faecalis)               | (1 min.)  |
| ➤ Pseudomonas aeruginosa                                 | (1 min.)         | ➤ HBV*<br>(Hepatitis B Virus)  | (1 min.)  |
| ➤ Salmonella enterica                                    | (1 min.)         | ➤ HCV*<br>(Hepatitis C Virus)  | (1 min.)  |
| ➤ Escherichia coli (E. coli)                             | (1 min.)         | ➤ RSV*<br>(Respiratory Syncytial Virus)                                | (1 min.)  |
| ➤ Escherichia coli O157:H7                               | (1 min.)         | ➤ HIV-1* (AIDS virus)  | (1 min.)  |
| ➤ Avian Influenza A Virus*<br>(H3N2)                     | (30 sec.)        | ➤ Human Coronavirus*   | (30 sec.) |
| ➤ Influenza A Virus*<br>(Hong Kong)                      | (30 sec.)        | ➤ Adenovirus type 2*   | (1 min.)  |
| ➤ Herpes Simplex Virus type 2*<br>(genital herpes virus) | (1 min.)         | ➤ Vaccinia virus*  | (1 min.)  |
| ➤ Candida albicans                                       | (1 min.)         | ➤ Pandemic 2009 H1N1 influenza A<br>Virus* (formerly called swine flu) | (30 sec.) |
| ➤ Proteus mirabilis                                      | (1 min.)         |  |           |
| ➤ Campylobacter jejuni                                   | (1 min.)         |  |           |
| ➤ Burkholderia cepacia                                   | (1 min.)         |  |           |

### ACTIVE INGREDIENTS

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride ..... 0.12%  
n-alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride ..... 0.12%  
Isopropyl alcohol ..... 63.25%

**OTHER INGREDIENTS** ..... 36.51%

**TOTAL INGREDIENTS**..... 100.00%



KEEP OUT OF REACH OF CHILDREN

### WARNING

See back panel for additional precautionary statements

EPA Reg. No. 10492-4

EPA Est. No.

**DisCide ULTRA Disinfecting Towelettes** meet the disinfection requirements of OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

**NET CONTENTS: 1 lb 12 oz**  
**60 Towelettes (10 x 10 in.)**

**1 lb 14 oz**  
**160 Towelettes (6 x 6.75 in.)**

## (BACK PANEL)

### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### General Precautions and Restrictions

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

[dispenser] **TO START FEED:** Remove large cover from container and discard seal. From center of towelette roll, pull up a towelette corner, twist into a point and thread through hole in container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When not in use, keep small center cap closed to prevent moisture loss.

**TO CLEAN, DECONTAMINATE, AND DISINFECT:** Remove gross dirt and soil. Thoroughly wipe the surface with DisCide ULTRA Disinfecting Towelette. Allow surface to remain wet for one minute.

**Healthcare For Disinfection and Deodorization of:** inanimate, hard, non-porous surfaces such as chairs, stools, counter tops, drawer pulls, door knobs and handles, carts, baskets, tables, cabinets, lighting fixtures, bassinets, bed rails, incubators, physical therapy equipment, shower stalls, toilet exteriors and toilet seats, telephones and other related hard surfaces in hospitals, operating and surgical rooms, intensive and critical care units, emergency units, dental and veterinary offices, surgery, recovery, anesthesia, X-Ray, Cat. Lab, blood collection and donation centers, isolation units, orthopedics, newborn nursery, respiratory therapy, radiology, pediatrics, physical therapy, rehabilitation, ophthalmology, optometry, hospices, central supply, emergency medical vehicles, police and fire vehicles, correctional facilities, funeral homes, morgues, spas, health clubs, salons, schools and school medical facilities, school buses, day care and non-food-contact surfaces. DisCide ULTRA Disinfecting Towelettes may be used to preclean or decontaminate medical instruments prior to sterilization or high-level disinfection.

**Consumer For Disinfection and Deodorization of:** inanimate, hard, non-porous kitchen/food service and bathroom surfaces such as counter tops, drawer pulls, carts, baskets, tables, cabinets, door knobs and handles, appliance exteriors, shower stalls, toilet exteriors and toilet seats, bathroom and lighting fixtures, sinks, flooring, walls, vanities, diaper pails, trash cans, telephones, shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, and other related hard, non-food-contact surfaces.

Use on stainless steel, glass, formica and other similar surfaces. Use care when using on varnished surfaces or plexi-glass. DO NOT USE AS A BABY WIPE. Discard towelette after use.

#### \*Virucidal Activity:

DisCide Ultra Disinfecting Towelettes are effective against the following viruses in 30 seconds or one minute when used according to label directions on hard, non-porous environmental surfaces: Avian Influenza A virus (H3N2), Influenza A virus (Hong Kong), Pandemic 2009 H1N1 influenza A virus (formerly called swine flu), RSV, HBV, HCV, Human coronavirus, HIV-1, Adenovirus type 2, Vaccinia virus, and Herpes Simplex virus type 2.

Kills HIV-1, HBV, and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

#### **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS), HBV, and HCV FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS**

**PERSONAL PROTECTION:** Wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling HIV-1, HBV, and HCV infected blood or body fluids.

**CLEANING PROCEDURE:** All blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. A DisCide ULTRA Disinfecting Towelette can be used for this purpose.

**CONTACT TIME:** Thoroughly wet surface with a DisCide ULTRA Disinfecting Towelette. Allow surfaces to remain wet for 1 minute, then air dry. The efficacy of a 1 minute contact time has been shown to be adequate against HIV-1 (AIDS virus), HBV, and HCV.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

**PRECAUTIONARY STATEMENTS:**

Hazards to Humans and Domestic Animals: **WARNING.** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Physical or Chemical Hazards: Flammable. Keep away from heat or open flame.

**FIRST AID**

**If in eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chem•Tel Inc. at 1-800-255-3924.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**PESTICIDE STORAGE:** Store away from heat.

**CONTAINER DISPOSAL:** [dispenser] Do not reuse towelette or empty container. Wrap towelette container and discard in trash. [foil packages] Do not reuse towelette or empty packet. Dispose of used towelette and packet in trash.

For technical information on DisCide ULTRA Spray, Towelettes, Aerosols, and DisCide XRA Hand Sanitizing Wipes, call 1-800-344-6424 or fax 203-377-8988.

PALMERO HEALTHCARE, LLC  
120 GOODWIN PLACE, STRATFORD, CT 06615  
[www.palmerohealth.com](http://www.palmerohealth.com)

**Emerging Viral Pathogen Claims**

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses

<b><i>For an emerging viral pathogen that is an...</i></b>	<b><i>...follow the directions for use for the following organisms on the label</i></b>
Enveloped Virus	Adenovirus type 2

DisCide ULTRA Disinfecting Towelettes has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, DisCide ULTRA Disinfecting Towelettes can be used against [name of emerging virus] when used in accordance with the directions for use against Adenovirus type 2 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. DisCide ULTRA Disinfecting Towelettes kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Adenovirus type 2 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

## Optional Text

- Hepatitis B Virus (as duck HBV)
- Hepatitis C Virus (ATCC VR-1422)
- Human Coronavirus (ATCC VR-740)
- HIV-1 (AIDS virus)
- Adenovirus type 2 (ATCC VR-864)
- Herpes Simplex Virus type 2 (ATCC VR-734)
- Avian Influenza A Virus (H3N2) (ATCC VR-2072)
- Influenza A Virus (Hong Kong) (ATCC VR-544)
- Respiratory Syncytial Virus (ATCC VR-26)
- Vaccinia Virus (ATCC VR-119)
- Vancomycin Resistant Enterococcus faecalis (ATCC 51559)
- Methicillin Resistant Staphylococcus aureus (ATCC 33592)
- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- Escherichia coli (ATCC 11229)
- Mycobacterium bovis (ATCC 27289)
- Candida albicans (ATCC 10231)
- Proteus mirabilis (ATCC 9240)
- Campylobacter jejuni (ATCC 29428)
- Burkholderia cepacia (ATCC 25416)
- Escherichia coli O157:H7 (ATCC 35150)